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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/510,514 | 11/01/2004 | Hoon Choi | 1599-0269PUS1 | 8899 |

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EXAMINER

BALLS, ROBERT J

ART UNIT PAPER NUMBER

1625

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/510,514 | Applicant(s) CHOI ET AL. | |
| | Examiner James Balls | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

1. Claims 1 - 11 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. §103(a), which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 – 11 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,869,670 in view of *Khomutov et al. (Novel acid-free cleavage of N-(2-hydroxyarylidene) protected amines*, Tetrahedron Lett., 42:2887-2889 (2001)).

Applicants claim a process for preparing Gemifloxacin by combining a quinolone and a pyrrolidine oxime. The Pyrrolidine oxime has a free NH₂-group, which must be protected to prevent it from interacting with the quinolone to produce unwanted impurities. As an NH₂-protecting group, applicants claim using aldehydes and ketones, which interact with the NH₂-group to produce a Schiff base. After properly combining the quinolone and pyrrolidine oxime, the Schiff base is cleaved by acid hydrolysis to afford the desired product.

Applicants' previous patent, U.S. Patent No. 5,869,670 teaches the synthesis of Gemifloxacin from the same pyrrolidine oxime and quinolone using a variety of different protecting groups to prevent unwanted interaction with the pyrrolidine oxime's free NH_2 -group. However, this patent does not teach using a Schiff base-type protecting group. *Khomutov et al.* does teach using a Schiff base to protect NH_2 -groups (see *Khomutov et al.*, p. 2888, first full paragraph). *Khomutov et al.* also explains that cleavage of the Schiff base by acid hydrolysis is well established and common in the art (see *Khomutov et al.*, p. 2887, first paragraph). The aldehyde *Khomutov et al.* used to form the Schiff-base, 2-hydroxybenzaldehyde, is encompassed by applicants' Claim 1 (and its dependent claims) and specifically named in Claim 3.

Motivation to combine U.S. Patent No 5,869,670 and *Khomutov et al.* is found in the need to protect pyrrolidine oxime's primary amine group while leaving its secondary amine group available to react with the quinolone. 2-hydroxybenzaldehyde reacts exclusively with NH_2 to form a Schiff base even in the presence of a secondary amine (see page 2888, first full paragraph). Thus, It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to protect the starting pyrrolidine oxime's primary amine group using a Schiff base to selectively protect the primary amine and prevent unwanted impurities.

Double Patenting

3. Claims 1 - 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 - 2 of U.S. Patent No. 5,869,670 in view of *Khomutov et al. (Novel acid-free cleavage of N-(2-hydroxyarylidene) protected amines*, Tetrahedron Lett., 42:2887-2889 (2001)) for the reasons given above.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

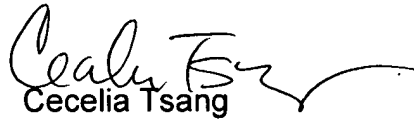
Conclusion

4. No claims are allowed.
5. Claims 1 – 11 are rejected under 35 U.S.C. §103.
6. Claims 1 – 11 are rejected under the judicially created doctrine of obviousness-type double patenting.
7. Other references included on the Notice of References Cited are provided to show the level of skill in the art at the time the claimed invention was made.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Balls whose telephone number is (571) 272-7997. The examiner can normally be reached on Mon - Fri 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James Balls
Art Unit 1625
February 13, 2006


Cecelia Tsang
Supervisory Patent Examiner
Art Unit 1625